Pliant Therapeutics Receives Orphan Designation from the European Medicines Agency for Bexotegrast (PLN-74809) for the Treatment of Idiopathic Pulmonary Fibrosis

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SOUTH SAN FRANCISCO, Calif., Dec. 15, 2022 (GLOBE NEWSWIRE) -- Pliant Therapeutics (NASDAQ: PLRX) announced today that its lead drug candidate, bexotegrast (PLN-74809), an oral, once daily, dual-selective αvß6/αvß1 integrin inhibitor, has received Orphan Drug Designation from the European Medicines Agency (EMA) for the potential treatment of idiopathic pulmonary fibrosis (IPF). Bexotegrast is currently being tested in the INTEGRIS-IPF Phase 2a clinical trial in IPF. Pliant presented positive data from the first three dose cohorts of this randomized, double-blind, placebo-controlled trial in July and anticipates topline 12-week data from the 320 mg cohort of patients with IPF, in the first quarter of 2023.

“Following the positive interim results from our Phase 2a trial of bexotegrast, we are pleased to receive the EMA's orphan medicinal product designation,” said Éric Lefebvre, M.D., Chief Medical Officer at Pliant Therapeutics. “This designation acknowledges the unmet need in IPF, as well as the potential of bexotegrast, and represents an important milestone in the clinical development of this novel drug. We look forward to continuing our work with the EMA and regulators around the globe to advance this therapy for patients in need.”

Orphan Medical Product Designation, granted by the EMA Committee, is designed to encourage the development of new treatments for rare conditions. To qualify, an investigational medicine must target a seriously debilitating or life-threatening condition affecting fewer than five in 10,000 people in the European Union (EU) and must show sufficient non-clinical or clinical data to suggest it may produce clinically relevant outcomes. Benefits of the EMA's Orphan Drug Designation include trial design assistance, a centralized EU approval process, and 10 years of market exclusivity. Bexotegrast received Orphan Drug Designation from the United States Food and Drug Administration (FDA) in 2018.

Background on Idiopathic Pulmonary Fibrosis

IPF is a chronic, progressive, fibrosing lung disease of unknown cause with few treatment options and a poor prognosis. Patients experience debilitating symptoms, including shortness of breath and difficulty performing daily activities, such as walking and talking. Currently, there is no pharmacological cure for IPF with neither of the approved two therapies demonstrating an ability to stop the progression of IPF. Therefore, there is a high unmet need for new therapeutic options to address the symptoms and modify the disease progression of this grievous illness.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical stage biopharmaceutical company focused on discovering and developing novel therapies for the treatment of fibrosis. Pliant's lead product candidate, PLN-74809 (bexotegrast), is an oral small molecule dual selective inhibitor of αvß6 and αvß1 integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. Bexotegrast (PLN-74809) has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and PSC and Orphan Drug Designation from the European Medicines Agency in IPF and PSC. Pliant is currently conducting Phase 2a trials of bexotegrast (PLN-74809) in the lead indications of IPF and PSC. Pliant has also developed PLN-1474, a small molecule selective inhibitor of αvß1 for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis, which Pliant has transferred to Novartis pursuant to our development partnership. In addition to clinical stage programs, Pliant currently has two preclinical programs targeting oncology and muscular dystrophies. For additional information about Pliant Therapeutics, visit www.PliantRx.com and follow us on Twitter, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those regarding development of bexotegrast, future interactions with the EMA, potential benefits of Orphan Medical Drug Designation by the EMA and anticipated timing of future clinical results for bexotegrast. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Pliant Therapeutics could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those related to the development and commercialization of our product candidates, including any delays in our ongoing or planned preclinical or clinical trials, the impact of the ongoing COVID-19 pandemic on our business, operations, clinical supply and plans, our reliance on third parties for critical aspects of our development operations, the risks inherent in the drug development process, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, and our ability to obtain and maintain intellectual property protection for our product candidates. These and additional risks are discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K filed for the year ended December 31, 2021 with the SEC on March 1, 2022, as updated by our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, which we filed with the SEC on November 8, 2022, each available on the SEC's website at www.sec.gov. Unless otherwise noted, Pliant is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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